PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

12

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
53593/001		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB00/03606	20/09/2000	21/09/1999
International Patent Classification (IPC) or national classification and IPC A61L2/20		
Applicant MICROFLOW LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 16 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☒ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
19/03/2001	16.01.2002
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Connor, M Telephone No. +49 89 2399 8402

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/03606

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

3,4,9,11,13,14	as originally filed			
1,2,5,6,6A,7,7A, 8,10,12	as received on	13/12/2001	with letter of	12/12/2001

Claims, No.:

1-22	as received on	13/12/2001	with letter of	12/12/2001

Drawings, sheets:

1/2,2/2	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-22
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-22
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-22
	No:	Claims	

2. Citations and explanations
   see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

   see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

R It m V

Reasoned statement under Article 35(2) with regard to novelty, inventive st p or industrial applicability; citations and explanations supporting such statement

1 The following documents are referred to in the present opinion:

D1: US-A-5 906 794 (CHILDERS ROBERT W) 25 May 1999 (1999-05-25)
D2: EP-A-0 774 263 (MDH LTD) 21 May 1997 (1997-05-21)
D3: US-A-5 173 258 (CHILDERS ROBERT W) 22 December 1992 (1992-12-22)

2 The amendments and basis thereof filed with applicant's letter dated 13.12.2001 were not clearly indicated as requested in point V-6 of the first opinion dated 13.08.2001. In view of the extensive amendments carried out, it cannot be ensured that all of them comply with the requirements of Article 34(2)(b) PCT. To the best of the examiner's knowledge, however, it would seem that said requirements were fulfilled. The applicant will probably be requested to identify said amendments and basis thereof should the present application be filed in any national or regional phase.

3 The subject matter of claim 16 is considered to be both novel and inventive in the sense of Article 33(2)&(3) PCT for the following reasons.

3.1 D1, considered to form the closest prior art, discloses an apparatus similar to the one called for in claim 16 of the present application, differing therefrom in that

(a) the means to deactivate the sterilant (D1: #20) is located in the main flow circuit whilst in the present application, it is located in one of the parallel branches (element #22 in branch #17 of Figure 1 of the present application);
(b) the means to supply the sterilant vapour (D1: #18) and to heat the gas (D1: #58) are not located in the second parallel branch as in Figure 1 of the present application; the foregoing means (D1: #18, 20, and 58) being located in the main 'single track' flow portion of the closed loop circuit.

3.2 The problem identified in the apparatus disclosed in D1 is that since the converter #20 to destroy H_2O_2 is placed on the main flow path straight at the exit of the sealed chamber, the building up of a sufficient level of concentration of decontaminant vapour in the chamber to achieve condensation in the chamber (and thence sterilisation) is a slow process.

3.3 In order to solve the problem stated in point V-3.2 supra, the sterilant deactivator #22 (corresponding to #20 in D1) of the apparatus called for in claim 16 of the present application is placed in a parallel track #17 which can be short circuited. This way, when it is required to build up the concentration of sterilant vapour in the sealed chamber, all the air is directed to the path #18 containing the device #27 for adding sterilant vapour to the circulating air and sterilant is added continuously as the air circulates with no removal of the sterilant vapour exiting from the chamber until the requisite amount of condensation of sterilant vapour has occurred in the chamber.

3.4 As the apparatus disclosed in D1 does not allow the continuous circulation of sterilant in the circuit, the apparatus called for in claim 16 of the present application is considered to be inventive in view of D1.

4 The subject matter of claim 1 is considered to be both novel and inventive for the same reasons as presented in point 3 supra for claim 16.

5 The disclosure of D2 and D3 is considered to be less relevant as condensation of the sterilant is not specified in D2 and is not recommended in D3 (cf. D3, col. 8, ll. 67-68), the latter thus leading the skilled person away from the subject matter of the claims in file.

Re Item VI

Certain documents cited

1 The following document has been mentioned in the search report as a P-document:

D4: WO 00 38745 A (ETHICON INC) 6 July 2000 (2000-07-06)

The validity of the priority date of the present application has not been checked. It must be mentioned, however, that D4 seems to disclose all the essential features called for in claim 1 of the present application.

Re Item VII

Certain defects in the international application

1 The description should be adapted to the new set of claims (Article 5 PCT). This includes p. 1, l. 1: **one** method only is concerned in the present application; the

singular form would therefore be more appropriate.

2 According to the requirements of Rule 11.13(l) reference signs not appearing in the drawings shall not appear in the description. This requirement is not met in view of the reference sign #11, mentioned on p. 8, last §.

3 There is no strict typographical format regulation for references to books and journal articles. They should, however, be consistent throughout one same document. This is not the case in the present application as Schumb, cited on p. 2, §3, is the only author cited in the whole application using small caps.

INTERNATIONAL SEARCH REPORT

Interna[redacted] Application No
PCT/[redacted]00/03606

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 173 258 A (CHILDERS ROBERT W) 22 December 1992 (1992-12-22) cited in the application column 2, line 36 - line 64 column 3, line 27 - line 46 column 7, line 26 - line 48	1-8, 16-18,20
P,X	WO 00 38745 A (ETHICON INC) 6 July 2000 (2000-07-06) page 2, line 25 -page 3, line 14 page 5, line 25 -page 6, line 21	1-8, 16-18,20

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

...patent family members

Interna... Application No
PCT 00/03606

Patent docum nt cited in search report	Publication date	Patent family m mber(s)	Publication date
US 5906794 A	25-05-1999	US 5876664 A	02-03-1999
EP 0774263 A	21-05-1997	GB 2308066 A	18-06-1997
US 5173258 A	22-12-1992	DE 69029660 D	20-02-1997
		DE 69029660 T	24-04-1997
		EP 0486623 A	27-05-1992
		WO 9105573 A	02-05-1991
WO 0038745 A	06-07-2000	AU 2395500 A	31-07-2000
		AU 2715800 A	31-07-2000
		WO 0038746 A	06-07-2000

INTERNATIONAL SEARCH REPORT

Intern. Application No
PCT/GB 00/03606

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61L2/20 A61L2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ, FSTA, INSPEC, COMPENDEX

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 906 794 A (CHILDERS ROBERT W) 25 May 1999 (1999-05-25) column 2, line 30 - line 63 column 3, line 8 - line 38 column 6, line 8 - line 65 figure 6 ---	1-18,20, 21
X	EP 0 774 263 A (MDH LTD) 21 May 1997 (1997-05-21) abstract column 2, line 15 -column 3, line 34 column 3, line 56 -column 4, line 29 figure 1 --- -/--	1-19

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
1 December 2000	11/12/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl. Fax: (+31-70) 340-3016	Menidjel, R

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Interna Application No
PCT 00/03606

C.(Continuation) DOCUMENTS CONSIDERED RELEVANT

Category *	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
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P,X	WO 00 38745 A (ETHICON INC) 6 July 2000 (2000-07-06) page 2, line 25 -page 3, line 14 page 5, line 25 -page 6, line 21	1-8, 16-18,20

INTERNATIONAL SEARCH REPORT

...nation on patent family members

Interna... Application No
PCT/GB 00/03606

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5906794 A	25-05-1999	US 5876664 A	02-03-1999
EP 0774263 A	21-05-1997	GB 2308066 A	18-06-1997
US 5173258 A	22-12-1992	DE 69029660 D	20-02-1997
		DE 69029660 T	24-04-1997
		EP 0486623 A	27-05-1992
		WO 9105573 A	02-05-1991
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		AU 2715800 A	31-07-2000
		WO 0038746 A	06-07-2000

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
53593/001		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB00/03606	20/09/2000	21/09/1999

International Patent Classification (IPC) or national classification and IPC
A61L2/20

Applicant
MICROFLOW LIMITED et al.

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

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   - I ☒ Basis of the report
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   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☒ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
19/03/2001	16.01.2002
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Connor, M Telephone No. +49 89 2399 8402

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/03606

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

3,4,9,11,13,14	as originally filed			
1,2,5,6,6A,7,7A, 8,10,12	as received on	13/12/2001	with letter of	12/12/2001

Claims, No.:

1-22	as received on	13/12/2001	with letter of	12/12/2001

Drawings, sheets:

1/2,2/2	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

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   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-22
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-22
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-22
	No:	Claims	

2. Citations and explanations
   see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

   see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 The following documents are referred to in the present opinion:

D1: US-A-5 906 794 (CHILDERS ROBERT W) 25 May 1999 (1999-05-25)
D2: EP-A-0 774 263 (MDH LTD) 21 May 1997 (1997-05-21)
D3: US-A-5 173 258 (CHILDERS ROBERT W) 22 December 1992 (1992-12-22)

2 The amendments and basis thereof filed with applicant's letter dated 13.12.2001 were not clearly indicated as requested in point V-6 of the first opinion dated 13.08.2001. In view of the extensive amendments carried out, it cannot be ensured that all of them comply with the requirements of Article 34(2)(b) PCT. To the best of the examiner's knowledge, however, it would seem that said requirements were fulfilled. The applicant will probably be requested to identify said amendments and basis thereof should the present application be filed in any national or regional phase.

3 The subject matter of claim 16 is considered to be both novel and inventive in the sense of Article 33(2)&(3) PCT for the following reasons.

3.1 D1, considered to form the closest prior art, discloses an apparatus similar to the one called for in claim 16 of the present application, differing therefrom in that

(a) the means to deactivate the sterilant (D1: #20) is located in the main flow circuit whilst in the present application, it is located in one of the parallel branches (element #22 in branch #17 of Figure 1 of the present application);
(b) the means to supply the sterilant vapour (D1: #18) and to heat the gas (D1: #58) are not located in the second parallel branch as in Figure 1 of the present application; the foregoing means (D1: #18, 20, and 58) being located in the main 'single track' flow portion of the closed loop circuit.

3.2 The problem identified in the apparatus disclosed in D1 is that since the converter #20 to destroy H_2O_2 is placed on the main flow path straight at the exit of the sealed chamber, the building up of a sufficient level of concentration of decontaminant vapour in the chamber to achieve condensation in the chamber (and thence sterilisation) Is a slow process.

3.3 In order to solve the problem stated in point V-3.2 supra, the sterilant deactivator #22 (corresponding to #20 in D1) of the apparatus called for in claim 16 of the present application is placed in a parallel track #17 which can be short circuited. This way, when it is required to build up the concentration of sterilant vapour in the sealed chamber, all the air is directed to the path #18 containing the device #27 for adding sterilant vapour to the circulating air and sterilant is added continuously as the air circulates with no removal of the sterilant vapour exiting from the chamber until the requisite amount of condensation of sterilant vapour has occurred in the chamber.

3.4 As the apparatus disclosed in D1 does not allow the continuous circulation of sterilant in the circuit, the apparatus called for in claim 16 of the present application is considered to be inventive in view of D1.

4 The subject matter of claim 1 is considered to be both novel and inventive for the same reasons as presented in point 3 supra for claim 16.

5 The disclosure of D2 and D3 is considered to be less relevant as condensation of the sterilant is not specified in D2 and is not recommended in D3 (cf. D3, col. 8, ll. 67-68), the latter thus leading the skilled person away from the subject matter of the claims in file.

Re Item VI

Certain documents cited

1 The following document has been mentioned in the search report as a P-document:

D4: WO 00 38745 A (ETHICON INC) 6 July 2000 (2000-07-06)

The validity of the priority date of the present application has not been checked. It must be mentioned, however, that D4 seems to disclose all the essential features called for in claim 1 of the present application.

Re Item VII

Certain defects in the international application

1 The description should be adapted to the new set of claims (Article 5 PCT). This includes p. 1, l. 1: **one** method only is concerned in the present application; the

singular form would therefore be more appropriate.

2 According to the requirements of Rule 11.13(l) reference signs not appearing in the drawings shall not appear in the description. This requirement is not met in view of the reference sign #11, mentioned on p. 8, last §.

3 There is no strict typographical format regulation for references to books and journal articles. They should, however, be consistent throughout one same document. This is not the case in the present application as Schumb, cited on p. 2, §3, is the only author cited in the whole application using small caps.

IMPROVEMENTS IN OR RELATING TO METHODS AND APPARATUS FOR VAPOUR PHASE STERILISATION

The present invention relates to methods and apparatus for sterilising the interior of a chamber using either a two component or a multi-component vapour, one component of which will be water.

There are numerous applications for sterilising the interior of a chamber including its contents in the pharmaceutical, biotechnology, and food industries, as well as the medical world. A number of compounds have been used as sterilising agents some of which are only partially effective and some of which have serious side effects because they are toxic, corrosive, or can cause other environmental damage. Formaldehyde has long been used as a cheap and quite effective sterilising agent but doubts over its safety and environmental persistence may prevent continued use. Hydrogen peroxide is a simple and cheap compound with good sterilising properties. Its major advantage is that it can be decomposed to water and oxygen, which are totally harmless products. In the vapour phase, hydrogen peroxide can be used to treat work areas of size from safety cabinets to clean rooms. In all gas phase sterilisation, deep layers of contamination will not be effected and good cleaning procedures are necessary as a preliminary to gas phase sterilisation.

Hydrogen peroxide gas sterilisation and decontamination systems have been designed in order to avoid condensation, and as such both flow through and recirculating systems have been so organised as to keep the vapour concentrations, especially of water, below the dew point. Examples of such systems are described in EP-A-0486623B1, GB-B-2217619, WO89/06140 and GB- A-2308066.

More recent work has shown that for rapid surface sterilisation and decontamination in rooms and smaller chambers, or isolators, condensation of a mixture of vapours of a gaseous decontaminant such as hydrogen

peroxide and water is essential. It is now believed that gaseous surface sterilisation using hydrogen peroxide is a condensation process so it would seem sensible to examine the process, to see how it may be optimised to take advantage of the condensation process. This knowledge may then be applied not only the sterilisation process using hydrogen peroxide gas but also other mixtures of sterilising gases that rely on condensation for their activity.

In the apparatus described in EP-A-0 486 623 B1 the air/gas mixture is circulated through the sealed chamber to be sterilised and then through the apparatus to produce and control the gas mixture. The gas returning to the apparatus is cleansed of any hydrogen peroxide gas and also dried before more water vapour and hydrogen peroxide gas are added. This cleansing and drying process is likely to be wasteful, as the vapours removed from the circulating gas must be replaced so that condensation may occur in the sealed chamber. The only reason for the removal of these vapours would be if the concentration of the hydrogen peroxide gas had been reduced because of decomposition.

It is now well understood that vapour phase decomposition does not occur at room temperatures, such homogenous decomposition only happens at elevated temperatures as reported in the paper "HYDROGEN PEROXIDE" by Walter C. Schumb, CHARLES N. SATTERFIELD, and RALPH L. WENTWORTH, published in AMERICAL CHEMICAL SOCIETY, MONOGRAPH SERIES, Catalog Card Number 55-7807, Chapter 8. Decomposition does however happen on surfaces, which are catalytic, but this appears to be very small amounts. To date no observer has seen a measurable increase in oxygen concentration, and the measured hydrogen peroxide gas concentrations conform very closely to the saturated vapour pressures of the original aqueous solution that is evaporated into the air stream. All of the indications are therefore that the amount of vapour phase decomposition of hydrogen peroxide is very small.

during the critical sterilisation phase of the cycle.

US-A-5906794 discloses a flow-through vapour phase sterilisation system which includes a sealable chamber with an inlet port and outlet port and a circuit fluidly connected to the chamber ports to provide a closed loop flow path for recirculating a carrier gas into through and out of the chamber. The system also includes a liquid sterilant vaporiser unit for delivering a vaporised liquid sterilant into the carrier gas flow upstream of the inlet port and a converter for converting the sterilant vapour to a form suitable for disposal is fluidly connected to the conduit circuit downstream of the chamber outlet port. A drying unit is included in the circuit downstream of the converter and has a valve for controlling flow to a first flow path through an air dryer and thence to the vaporiser or a second flow path which by passes the air dryer. By varying the amount of fluid through the first and second flow paths a selected portion of the carrier gas can be routed to by pass the dryer and the humidity of the carrier gas can be regulated to maintain a predetermined percent saturation sterilant vapour in the chamber as the sterilising cycle proceeds.

It is an object of the present invention to provide a sterilising system in which concentration of sterilant in the chamber to be sterilised is built up more rapidly to achieve condensation of sterilant in the chamber.

This invention provides a method of sterilising a sealable enclosure comprising the steps of circulating a carrier gas and sterilant through the enclosure and through a flow path having an outlet from the enclosure and an inlet to the enclosure, any sterilant in the gas flow received from the enclosure being rendered suitable for disposal, and the content of water vapour being reduced following which the gas

flow is heated and further sterilant is added to sterilise the enclosure, wherein the flow path has two parallel branches in one of which any sterilant in the gas flow is rendered suitable for disposal and any water vapour content in the gas is reduced and in the other of which the carrier gas is heated and sterilant is added to the gas, the method further comprising the steps of initially circulating said carrier gas through said one branch, monitoring the moisture content of the gas in the enclosure and terminating flow of carrier gas through said one branch when the relative humidity in the enclosure has been reduced to a predetermined level such that the surfaces of the enclosure are relatively dry, initiating flow of the carrier gas through said other branch and adding a sterilant vapour or vapours to the gas passing through the other branch until condensation of the sterilant takes place in the enclosure, terminating supply of sterilant to the carrier gas, continuing to circulate the carrier gas substantially saturated with sterilant vapour for a predetermined time to ensure sterilisation of the enclosure terminating flow through said other branch and redirecting the flow of carrier gas through said one branch to extract the sterilant from the gas enclosure to render the sterilant suitable for disposal and to reduce the relative humidity of the carrier gas.

More specifically the invention provides a method of sterilising a sealable enclosure comprising the steps of initially reducing the relative humidity in the enclosure to about 30 to 40%, circulating a carrier gas to the enclosure, raising the temperature of the circulating gas above ambient, supplying a sterilant vapour or vapours to the circulating carrier gas sufficient to saturate substantially the gas whereby on cooling in the enclosure, a condensate of

the sterilant vapour is formed on surfaces in the enclosure, distributing the gas/vapour throughout the enclosure to ensure that the condensate is formed on all surfaces in the enclosure, measuring the amount of condensate formed on a surface of the enclosure and continuing to circulate the gas/vapour until a required amount of condensate has formed in the enclosure terminating supply of sterilant vapour to the gas whilst continuing to circulate the saturated gas/vapour to maintain the condensate on the surface for a predetermined period of time and finally extracting the sterilant vapour from the carrier gas whilst continuing to circulate the carrier gas through the enclosure to extract the condensate from the enclosure.

Preferably the sterilant vapour is extracted from the carrier gas by breaking down the vapour into disposable constituents.

It is also preferred that the sterilant vapour is hydrogen peroxide and water vapour. In this case the hydrogen peroxide extracted from the chamber with the circulating gas is subjected to catalytic action to break the hydrogen peroxide down into water vapour and oxygen, the former being extracted from the gas before the gas is recirculated through the enclosure.

The initial step of reducing the relative humidity in the enclosure may be carried out by circulating the carrier gas through the chamber and extracting water vapour from the circulating gas outside the chamber.

The relative humidity in the enclosure may be reduced initially to about 35%. In addition, the enclosure may be held at said reduced relative humidity for a period of time according to the size of enclosure and flow rate of gas to ensure dryness of said surfaces in the enclosure.

Entry to one branch is closed and entry to the other branch may be opened and vice versa to provide flow through one or other of the branches. For example, valve means may permit flow into one branch and not the other and vice versa.

Alternatively, pump means may be provided in said parallel branches and are used to cause gas flow along one or other of the parallel branches in the flow path.

The invention further provides apparatus for sterilising a sealable enclosure comprising a circuit for flow of a gas or gasses, the circuit having means to receive and connect an enclosure to be sterilised in the circuit to form a closed circuit therewith, means to circulate gas through the circuit and enclosure, and having two parallel branches in the circuit one of which contains means to deactivate a sterilant to be added to the carrier gas flowing through the circuit and means to dehumidify the gas and the other of which branches contains means to heat the gas and means to supply a sterilant vapour or

vapours to the gas, the apparatus further comprising control means for determining through which of the parallel branches the gas flows, the control means including means to determine the relative humidity of the gas exiting the enclosure and being operable to maintain flow through said one branch passage open until the relative humidity falls below a predetermined level and then to terminate flow through that branch and to initiate flow in the other branch and means to measure condensation in the enclosure to terminate flow in said other branch and to initiate flow in said one branch when the required amount of condensation has built up in the enclosure.

The apparatus may further include means to distribute the gas/vapours throughout the enclosure to ensure that the condensate is formed on all surfaces in the enclosure.

It has been found that in aqueous solutions of hydrogen peroxide

very fast kill rates are achieved even at 10% hydrogen peroxide concentrations with even faster kills at 20% solution. Since we believe that gaseous surface sterilisation is a micro condensation process, then it may be considered to be analogous to the work

" THE STERILISING EFFECT AGAINST BACILLUS SUBTILIS SPORES OF HYDROGEN PEROXIDE AT DIFFERENT TEMPERATURES AND CONCENTRATIONS;" by P. SWARTLING and B. LINDGREN J. DAIRY RES. (1968), 35,423. This gives a good guide as to the expected results that may be achieved with a gaseous condensation process.

This also suggests that should some small amount of decomposition occur because of surface catalysation of the gas then kills would still be achieved. In reality such decomposition appears to be very small indeed as indicated by the gas concentration data.

The following is a description of some specific embodiments of the invention, reference being made to the accompanying drawings in which:

Figure 1 is a diagrammatic view of a sealed chamber and a sterilisation circuit connected to the chamber for sterilising the interior and contents of the chamber using a gas carrying an aqueous vapour of a liquid sterilant, the circuit having two pumps or fans.

Figure 2 is a diagrammatic view of a sealed chamber and a further form of circuit connected to the chamber for sterilisation of the interior of the chamber and its contents using a gas containing an aqueous vapour of a liquid sterilant, the circuit having a single pump or fan.

The apparatus comprises a sealed chamber 10, and an apparatus included generally at 11 incorporating a dual circuit for dehumidification, sterilising and aeration of the sealed chamber 10. A carrier gas, i.e. air, and a sterilising gas or gases are drawn from the sealed chamber to the apparatus through sealed connections fluidly connecting the chamber to the

gas a suitable catalyst would be ruthenium on inert pellets which decomposes the gas to water vapour and oxygen.

A desiccant dryer may perform the dehumidification process, but a more suitable technique would be to reduce the gas temperature using a refrigeration system. The reduction in temperature causes the water vapour to condense with the products of decomposition. The resulting condensate and decomposition products may then be pumped away. It is necessary to raise the circulating gas temperature after dehumidification and an electric heater 24 or other heating means is placed downstream of the dehumidifier for the purpose.

In the second parallel branch is a heater 25 to raise the gas temperature prior to entering an evaporator 26, in which the liquid sterilant is turned to vapour by heating. A liquid sterilant supply 27 controls the liquid flow to the evaporator.

The heater 25 may be of a similar construction to the other heater 24. The evaporator is a flash evaporator in which the liquid sterilant is evaporated by dropping under gravity a stream of liquid onto a heated surface. The flow of liquid from the sterilant supply is fed onto the heated surface at a selected rate by using a variable speed pump, which is controlled from a flow measuring system. The gas temperature entering the sealed chamber 10 is measured at 28 using a standard temperature probe. Gas entry to the chamber 10 is through a gas distribution system including a rotating nozzle arrangement which projects gas at high temperature and velocity to every part of the chamber. In addition a system for control gas pressure in the circuit to raise or reduce pressure as required is provided.

The components in the alternative arrangement shown in Figure 2 are the same, with the same numbering except for the fan and valve arrangement. In Figure 2 the gas or gases are driven round the system by a single fan of pump 30. The gas or gas mixtures leaving the fan or pump

During the third and final phase of the sterilisation cycle the carrier gas together with the sterilising gas or gases is circulated through a system to render the active gases harmless, so that it may be taken away, whilst at the same time removing the water vapour in a dehumidifier. The clean carrier gas is then returned to the sealed chamber where it gathers more of the active gas or gases thus further reducing to the level of the active ingredients. This process continues until the amount of active ingredients have been reduced to an acceptable level.

1. The relative humidity (RH) must be controlled at the start of the sterilisation cycle. We have established that the optimum value is between 30 and 40%. There are two points to be considered about the starting value of RH, the first is to obtain the shortest possible cycle (this requires the RH to be reduced to about 35%), and the second is to achieve a repeatable cycle. The repeatability depends on using the same starting value of RH and this may well have to be higher than 35% depending on local conditions. As it may not always be practical to achieve a starting value of 35% for the RH then it is essential that the same starting value is always used. Higher values of RH will increase the time required to achieve sterilisation as the condensate forming on surfaces will be diluted by any water that is present.
2. The amount of condensation is important; if too much is formed, the time to remove the surface layer after sterilisation has been achieved will be increased, as it would take longer to dry the surfaces. If insufficient condensation is allowed to form then sterilisation will not take place. The accurate measurement of this surface layer is essential to the process.
3. From the work of Swartling et al referred to above, it is clear that some "soaking" time will be required for the condensed liquid to be effective. This is built into the sterilisation cycle as a dwell

Claims:

1. A method of sterilising a sealable enclosure comprising the steps of circulating a carrier gas and sterilant through the enclosure and through a flow path having an outlet from the enclosure and an inlet to the enclosure, any sterilant in the gas flow received from the enclosure being rendered suitable for disposal, and the content of water vapour being reduced following which the gas flow is heated and further sterilant is added to sterilise the enclosure, characterised in that the flow path has two parallel branches in one of which any sterilant in the gas flow is rendered suitable for disposal and any water vapour content in the gas is reduced and in the other of which the carrier gas is heated and sterilant is added to the gas, the method further comprising the steps of initially circulating said carrier gas through said one branch, monitoring the moisture content of the gas in the enclosure and terminating flow of carrier gas through said one branch when the relative humidity in the enclosure has been reduced to a predetermined level such that the surfaces of the enclosure are relatively dry, initiating flow of the carrier gas through said other branch and adding a sterilant vapour or vapours to the gas passing through the other branch until condensation of the sterilant takes place in the enclosure, terminating supply of sterilant to the carrier gas, continuing to circulate the carrier gas substantially saturated with sterilant vapour for a predetermined time to ensure sterilisation of the enclosure terminating flow through said other branch and redirecting the flow of carrier gas through said one branch to extract the sterilant

from the gas enclosure to render the sterilant suitable for disposal and to reduce the relative humidity of the carrier gas.

2. A method as claimed in claim 1, wherein entry to one branch is closed and entry to the other branch is opened and vice versa to provide flow through one or other of the branches.

3. A method as claimed in claim 2, wherein valve means permit flow into one branch and not the other and visa versa.

4. A method as claimed in claim 2, wherein pump means are used in the flow path to circulate said carrier gas.

5. A method as claimed in claim 2, wherein pump means are provided in said parallel branches and are used to cause gas flow along one or other of the parallel branches in the flow path.

6. A method as claimed in any of claim 1 to 5, wherein water vapour is removed from the gas in said one branch by cooling the gas to cause the water vapour to condense, the resulting condensate being removed.

7. A method as claimed in claim 6, wherein the gas cooled in said one branch is heated following said cooling step.

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8. A method as claimed in any of the preceding claims comprising the steps of initially reducing the relative humidity in the enclosure to about 30 to 40%, circulating a carrier gas to the enclosure, raising the temperature of the

circulating gas above ambient, supplying a sterilant vapour or vapours to the circulating carrier gas sufficient to saturate substantially the gas whereby on cooling in the enclosure, a condensate of the sterilant vapour is formed on surface in the enclosure, distributing the gas/vapour throughout the enclosure to ensure that the condensate is formed on all surfaces in the enclosure, measuring the amount of condensate formed on a surface of the enclosure and continuing to circulate the gas/vapour until a required amount of condensate has formed in the enclosure terminating supply of sterilant vapour to the gas whilst continuing to circulate the saturated gas/vapour to maintain the condensate on the surface for a predetermined period of time and finally extracting the sterilant vapour from the carrier gas whilst continuing to circulate the carrier gas through the enclosure to extract the condensate from the enclosure.

9. A method as claimed in claim 8, wherein the sterilant vapour is extracted from the carrier gas by breaking down the vapour into disposable constituents.

10. A method as claimed in claim 8 or 9, wherein the sterilant vapour is hydrogen peroxide and water vapour.

11. A method as claimed in claim 10, wherein the hydrogen peroxide extracted from the chamber with the circulating gas is subjected to catalytic action to break the hydrogen peroxide down into water vapour and oxygen, the former being extracted from the gas before the gas is recirculated through the enclosure.

12. A method as claimed in any of claims 8 to 11, wherein the initial step of reducing the relative humidity in the enclosure is carried out by circulating the carrier gas through the chamber and extracting water vapour from the circulating gas outside the chamber.

13. A method as claimed in any of claims 8 to 12, wherein the relative humidity in the enclosure is reduced to about 35%.

14. A method as claimed in any of claims 8 to 13, wherein the enclosure is held at said reduced relative humidity for a period of time according to the size of the enclosure and flow rate of gas to ensure dryness of said surfaces in the enclosure.

15. A method as claimed in any of claims 8 to 14, wherein the condensate is maintained on the surfaces within the enclosure for a predetermined period to ensure sterilisation of the surfaces.

16. An apparatus for sterilising a sealable enclosure (10) comprising a circuit (12) for flow of a gas or gasses, the circuit having means to receive and connect an enclosure to be sterilised in the circuit to form a closed circuit therewith, means (19,20) to circulate gas through the circuit and enclosure, and having two parallel branches (17, 18) in the circuit one of which contains means (22) to deactivate a sterilant to be added to the carrier gas flowing through the circuit and means (23) to dehumidify the gas and the other of which branches contains means (25) to heat the gas and means (26) to supply a sterilant vapour or

vapours to the gas, the apparatus further comprising control means (13 to 16) for determining through which of the parallel branches the gas flows, the control means including means (14) to determine the relative humidity of the gas exiting the enclosure and being operable to maintain flow through said one branch (17) passage open until the relative humidity falls below a predetermined level and then to terminate flow through that branch and to initiate flow in the other branch (18) and means (16) to measure condensation in the enclosure to terminate flow in said other branch and to initiate flow in said one branch when the required amount of condensation has built up in the enclosure.

17. An apparatus as claimed in claim 16, characterised in that a fan (20) provided in the circuit (12) between the enclosure (10) and the parallel branches (17, 18) of the circuit to cause gas flow around the circuit and valve means (31) are provided at the entry to the first and second branches which are selectively operable to permit flow through one or the other of the branches.

18. An apparatus as claimed in claim 16, fans (19, 20) are provided in both branches in the circuit which are selectively operable to cause flow of gas through one or other of the branches (17, 18).

19. An apparatus as claimed in any of claims 16 to 18, characterised in that means are provided to distribute the gas/vapours throughout the enclosure (10) to ensure that condensate is

formed on all surfaces in the enclosure.

20. An apparatus as claimed in any of claims 16 to 19, the means to deactivate the sterilant in said one branch comprise means (22) to break the sterilant extracted from the enclosure (10) down into disposable constituents.

21. An apparatus as claimed in claim 20, the sterilant is hydrogen peroxide vapour and water vapour and the means (22) to break the sterilant down comprise catalytic means to act on the hydrogen peroxide to break the hydrogen peroxide down into water vapour and oxygen.

22. An apparatus as claimed in any of claims 16 to 21, the means (23) to lower the relative humidity of the circulating carrier gas comprise refrigeration means to cool the gas to extract moisture therefrom by condensation and means (24) to heat the gas above ambient following said condensation process.

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 18 May 2001 (18.05.01)	
International application No. PCT/GB00/03606	**Applicant's or agent's file reference** 53593001/IA2512
International filing date (day/month/year) 20 September 2000 (20.09.00)	**Priority date** (day/month/year) 21 September 1999 (21.09.99)
Applicant MARTIN, Anthony, Michael et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

19 March 2001 (19.03.01)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Pascal Piriou
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
53593001/IA2512		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/GB 00/03606	20/09/2000	21/09/1999
Applicant		
MICROFLOW LIMITED		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [ ] the text is approved as submitted by the applicant.

   [X] the text has been established by this Authority to read as follows:

   METHODS AND APPARATUS FOR VAPOUR PHASE STERILISATION

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 1

   [X] as suggested by the applicant.

   [ ] None of the figures.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

INTERNATIONAL SEARCH REPORT

International Application No
PC[redacted] 00/03606

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61L2/20 A61L2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ, FSTA, INSPEC, COMPENDEX

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 906 794 A (CHILDERS ROBERT W) 25 May 1999 (1999-05-25) column 2, line 30 - line 63 column 3, line 8 - line 38 column 6, line 8 - line 65 figure 6 ---	1-18,20, 21
X	EP 0 774 263 A (MDH LTD) 21 May 1997 (1997-05-21) abstract column 2, line 15 -column 3, line 34 column 3, line 56 -column 4, line 29 figure 1 --- -/--	1-19

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
1 December 2000	11/12/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Menidjel, R

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PC[redacted]B 00/03606

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 173 258 A (CHILDERS ROBERT W) 22 December 1992 (1992-12-22) cited in the application column 2, line 36 - line 64 column 3, line 27 - line 46 column 7, line 26 - line 48	1-8, 16-18,20
P,X	WO 00 38745 A (ETHICON INC) 6 July 2000 (2000-07-06) page 2, line 25 -page 3, line 14 page 5, line 25 -page 6, line 21	1-8, 16-18,20

1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/GB 00/03606

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5906794 A	25-05-1999	US 5876664 A	02-03-1999
EP 0774263 A	21-05-1997	GB 2308066 A	18-06-1997
US 5173258 A	22-12-1992	DE 69029660 D	20-02-1997
		DE 69029660 T	24-04-1997
		EP 0486623 A	27-05-1992
		WO 9105573 A	02-05-1991
WO 0038745 A	06-07-2000	AU 2395500 A	31-07-2000
		AU 2715800 A	31-07-2000
		WO 0038746 A	06-07-2000